

REMARKS

Status of the Claims

Claims 2-6, 9-12, 14-17 and 19-37 are pending in this application. Claims 1, 7, 8, 13, 18, 28 (both occurrences thereof) and 29 have been canceled. No new claims have been added.

Restriction Requirement

The Examiner maintains the withdrawal of claims 2-6, 9-12 and 17 because of the election of the adsorbent and claims 15, 16 and 2-27. Applicants note that the Examiner mistakenly includes claim 14 in the list of withdrawn claims. It is noted that claim 14 is within the elected group, Group I. Applicants respectfully submit that withdrawn claims 2-6, 9-12, 17 and 20-27 should have been examined with claim 19. The adsorbent, a method of using the adsorbent and a column containing the adsorbent should all be examined together in view of the presence of the special technical feature, the adsorbent, which is present in all of these embodiments. Reconsideration of the restriction is respectfully requested.

Rejection under 35 USC 112, second paragraph

The Examiner rejects claim 19 because it is dependent from a non-elected claim. Applicants submit that this is an improper

rejection. There is nothing indefinite about the subject matter claimed in claim 19. Since the subject matter of the claim is particularly and distinctly recited. Thus, Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 USC 112, first paragraph

The Examiner rejects claim 19 as not enabled by the specification. The Examiner contends that the specification does not support a therapeutic use of a water insoluble matrix containing amino groups or carboxyl groups or sulfate groups for sepsis. The Examiner also states that there is no support for treating sepsis using carboxymethyl sephadex or diethylaminoethyl sepharose in combination with HMG antibodies. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Applicants submit that the Examiner has failed to meet the burden of presenting a *prima facie* case as to why the claims would not be enabled. See *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993). *Wright*, citing *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971) states

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO

meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.

The Examiner has failed to meet this initial burden. The Examiner incorrectly states that there is no literature to support the treatment of sepsis and that the skilled artisan would have expected failure. The Examiner also merely states that there is no guidance, no working examples and that the art is unpredictable without giving any explanation or reasons why the Examiner believes the above.

However, Applicants submit that even if the Examiner had met this burden, Applicants have provided literature references that disclose that sepsis is caused by the presence of HMG protein in mice and that removing HMG protein cures sepsis. See, for example, Wang et al. Science, 285, page 248 (1999), which is referenced on page 1, line 18 of the specification and also submitted in an Information Disclosure Statement. Also, removal of HMG protein from human blood serum is described in the specification. As such, Applicants submit that one of ordinary skill in the art would not have to engage in undue experimentation to practice the present invention.

Moreover, Applicants submit that in the absence of some evidence from the Examiner that removing HMG protein does not treat sepsis, one must assume that the full scope of the claimed

invention is enabled by the specification. As such, the rejection of claim 19 should be withdrawn.

Rejections under 35 USC 103(a)

The Examiner rejects claims 1, 7, 8, 13 and 19 as obvious over Stuber USP 5,116,962 (Stuber '962). The Examiner states that the adsorbent disclosed in Stuber '962 has sulfate groups that would adsorb HMG proteins. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness, because Stuber '962 fails to disclose or suggest an adsorbent that adsorbs HMG proteins where the adsorbent has a carrier material on which substances having a hydrogen-bondable functional group and/or a hydrophobic functional group immobilized on the material. As such, Applicants respectfully request withdrawal of the rejection over Stuber '962.

The Examiner also rejects claims 1 and 19 as obvious over Abbott USP 4,430,496 (Abbott '496). The Examiner states that Abbott '496 discloses an adsorbent with trimethylammonium groups. The Examiner states that the adsorbent of Abbott '496 would adsorb HMG proteins if the pH of the eluting buffer were above the isoelectric point (IEP) of the protein. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Again, Applicants submit that the Examiner has failed to establish a prima facie case of obviousness. Abbott '496 fails to disclose the specific adsorbent of the present invention that adsorbs HMG protein. Applicants submit that trimethyl ammonium groups do not fall within the scope of claim 19. Therefore, all of the elements of the present invention are neither disclosed nor suggested.

Applicants also submit that the pH of the column cannot be altered as the Examiner suggests because the body fluid, such as blood is treated and then the treated blood is returned to the body. Thus, the pH must remain constant and consistent with the pH of the blood. As such, Applicants submit that there is no motivation to alter Abbott '496 to arrive at the present invention because the invention would be inoperable if altered as suggested by the Examiner. Thus, no prima facie case of obviousness has been established.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the


telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By


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0760-0298P
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